

Cholesterol Test



Finger-prick
blood



Results
in 2 mins



Over 96%
accurate

Watch the
instruction
video



Intended use

The Newfoundland Cholesterol Test is a self-test to identify cholesterol levels in finger-prick blood. High cholesterol increases your risk of coronary artery disease, heart attacks and strokes.

General information

Cholesterol levels, alongside other factors, such as lifestyle and medical conditions, are used to evaluate your risk of cardiovascular disease. The levels you should aim for might be different depending on things such as your age, and whether you have conditions such as diabetes or cardiovascular disease. Please see the "Expected Values" section for reference levels. If your test result is not consistent with your expectations or you would like to discuss any concerns further, you should contact your GP.

Contents



1 Test

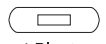
1 Capillary tube



1 Antiseptic wipe



2 Disposable lancets



1 Plaster



1 Instructions for use

Materials required but not provided:

- Timer
- Clean, dry tissue

Precautions

1. Read the instructions carefully before use. Incorrect operation can cause unreliable results.
2. Do not use after the expiry date or if the pouch has been damaged. The test should remain in the sealed pouch until use.
3. Store the test kit between 2°C and 30°C. Do not freeze. Keep away from heat and direct sunlight.
4. For self-testing in vitro diagnostic use only. Cannot be reused.
5. Do not touch the reagent area of the strip.
6. Not suitable for use on babies or infants.
7. Handle with care and dispose of all elements after use. The test kit contents should be placed safely in a bin and thrown away with your household waste.

Specimen preparation & collection

The Newfoundland Cholesterol Test is performed using blood collected from the fingertip. The blood sample should be tested immediately after collection. Do not press or squeeze the finger too hard as this will push fluid from the tissue into the blood and may cause false results.

Instructions

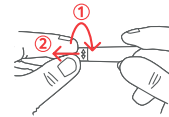
Preparation

1. Wash your hands with warm water and soap, carefully drying your hands afterwards.
Note: Use of lotions and hand creams should be avoided before testing.
2. Open the foil pouch and remove the test kit.
Note: Please ensure the test kit is facing the correct way up before testing.



Obtaining a blood sample

3. Hold the lancet and twist the white cap to remove.
Note: Be careful when removing the cap of the lancet that you twist it off. If you pull it, then it might prematurely fire the lancet rendering it unusable. Similarly, if you snap the cap off without twisting it, then you might break off the stem of the cap, again making the lancet unusable.
4. Use the antiseptic wipe provided to clean the finger that will be pricked with the lancet (the side of the ring finger is recommended). Massage your hand from the wrist to the fingertip to increase blood flow.
5. Place the lancet against the fingertip and press down firmly to draw blood. Replace the cap onto the used lancet and set aside.
6. Wipe away the first drop of blood with a clean tissue.
7. Collect the second drop of blood using the capillary tube to fill the line indicated. Apply the plaster to your finger if needed.



Note: Please check how to use the capillary tube first before using it.

Tips

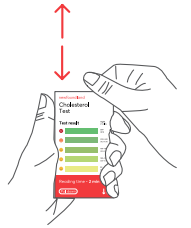
1. Hold the capillary tube horizontally and slightly downward.
2. Without squeezing, touch the tip of the pipette to the blood.
3. Capillary action will automatically draw the blood sample. You may need to massage your finger again if more blood is required. Collect to the fill line and stop.
4. Do not squeeze or block the air vent during collection of the blood sample.

Performing the test

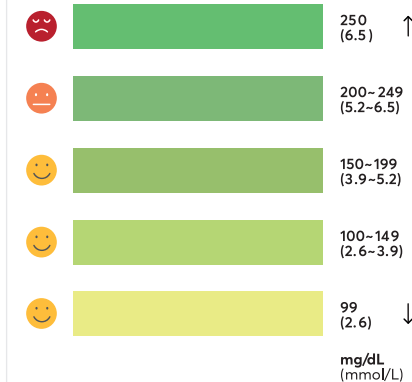
8. Gently squeeze the dropper to apply the blood sample into the sample well and wait for 2 minutes before turning the test kit over. **DO NOT** turn over the test kit before 2 minutes.
Note: Squeeze the bulb until all the blood in the capillary tube is applied. If you don't apply sufficient blood to the sample well, the result may be inaccurate. The sample well should be completely covered with blood. If the blood sample was smeared or too little blood was applied, you should dispose of the test kit and repeat the test with a new kit.



9. Turn over the test kit after 2 minutes and slide the colour chart to find the closest colour match within 30 seconds. This is your result.
Note: The test result must be read within 2 minutes 30 seconds of applying the blood sample. Results may be inaccurate if read too early or too late. A test area that appears lighter than the 99mg/dL colour block should be interpreted as a cholesterol result of less than 99mg/dL (i.e. low cholesterol). A test area that appears darker than the 250mg/dL colour block should be interpreted as a cholesterol result greater than 250mg/dL (i.e. high cholesterol).



** measurement range (99-250mg/dL (2.6~6.5 mmol/L))



Expected Values

Adults

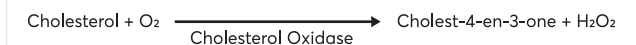
Desirable	Borderline high	High
<200 mg/dL (<5.18 mmol/L) : Desirable	200-239 mg/dL (5.18-6.19 mmol/L) : Borderline high	≥ 240 (≥ 6.22 mmol/L) : High

Children

Desirable	Borderline high	High
<170 mg/dL (<4.40 mmol/L) : Desirable	170-199 mg/dL (4.40-5.15 mmol/L) : Borderline high	≥ 200 (≥ 5.18 mmol/L) : High

Test principle

The Newfoundland Cholesterol Test is a semi-quantitative test based on an enzymatic reaction to measure total cholesterol. When whole blood is applied to the Newfoundland Cholesterol Test kit, a chemical reaction causes a colour change in the test area.



Chemical composition

- Cholesterol esterase 200 Unit • Cholesterol oxidase 45 Unit
- Peroxidase 100 Unit • Aminoantipyrine 0.1mg

Limitations of procedure

Studies were performed to test for substances that may interfere with these tests. The results are below:

Known interfering substances:

No significant effect was observed at the following concentration for each substance.

Ascorbic acid: 3 mg/dL

Bilirubin: 20 mg/dL

Creatinine: 30mg/dL

Hemoglobin: 400mg/dL

Urea: 500mg/dL

EDTA (Anticoagulant): 640mg/dL

Heparin-Lithium (Anticoagulant): 100mg/dL

Hematocrit: Between 30~55% has no effect on test results.

Drug: Dopamine, Gentisic acid and methyldopa may cause lower test results.

Performance Characteristics

Repeatability / Reproducibility:

A study was conducted using samples containing known cholesterol values.

Each sample was tested ten times with the Newfoundland Cholesterol Test kit. The agreement of results was above 93%.

Accuracy

A clinical study was conducted comparing the Newfoundland Cholesterol Test kit with the reference method (BECKMAN COULTER AU5800). This clinical study was performed using 80 venous blood samples. Comparison results between professional and laymen revealed a very high concordance of between 90~96%.

FAQs

Can the result give an incorrect reading?

Yes, you may get an incorrect result if:

- You compared the colours **before** 2 minutes or **after** 2 minutes 30 seconds.
- You performed the test in direct sunlight or in a humid environment (e.g. a steamy bathroom)
- The test kit was stored or used above the maximum temperature (30°C)
- You did not use sufficient blood to perform the test.

Do I need to fast before testing?

In general, fasting before your test is not required, unless you are already taking a cholesterol medication.

What do my total cholesterol numbers mean ?

Your test result will place you in one of 3 medical risk groups (please refer to "Expected Values" section). As a general guide, the NHS suggest that total cholesterol levels should be:

5mmol/L or less for healthy adults

4mmol/L or less for those at high risk

4mmol/L or less for healthy children

Your cholesterol level may vary if you are pregnant, take birth control or oestrogen replacement pills, or if you have certain medical conditions or recent illnesses.

A high total cholesterol level is just one risk factor for heart disease. Other risk factors include smoking, high blood pressure, a family history of heart disease, a diet high in saturated fats, and insufficient exercise.

What should I do if the total cholesterol level is higher than the normal value?

If your cholesterol result is high, you should speak with your GP to discuss further. Maintaining a healthy, balanced diet, taking regular exercise and abstaining from alcohol consumption and smoking can all help to reduce cholesterol.

Medical devices inside the kit

Lancet

STERILE R CE 0123



Shandong, Lianfa Medical Plastic Products Co., Ltd. No.1 Shuangshan Sanjian Road 250200 Zhangqiu City,Jinan, Shandong, China

EC REP

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Capillary tube

CE



Jiangsu Kehua Medical Instrument Technology Co Ltd, West Industrial Park, Wulie Town, Dongtai City, Jiangsu Province, China

EC REP

SUNGO Cert GmbH, Harffstr.47, 40591 Düsseldorf, Germany

Antiseptic wipe

STERILE R CE 0123



Jiangsu Sunclean Medical Co.,Ltd, No.11 Fenghuang South Road, Hutang Town, Wujin District, 213162 Changzhou City, Jiangsu Province, P.R. China

EC REP

Medpath GmbH Mies-van-der-Rohe Strasse 880807,
Munich, Germany

Adhesive plaster

STERILE EO STERILE R CE 2460 MD



Young Chemical Co.,Ltd, 80~93, Golden root-ro, Juchon-myeon, Gimhae-si, Gyeongsangnam-do, 50969, Republic of Korea

EC REP

MedEnvoy Global BV Prinsese Margrietplantsoen 33 Suite 123 2595 AM
The Hague, The Netherlands



Tests per kit



Temperature Limit



For in vitro diagnostic use



Lot Number



Use by



Catalogue number



Do not reuse



Do not use if package is damaged



Sterilised using irradiation



Read the instructions before use



CE Marking



Legal manufacturer



Authorised Representative
in the European Community



DFI Co., Ltd. 388-25, Gomo-ro, Jillye-myeon,
Gimhae-si, Gyeongsangnam-do, 50875,
Republic of Korea

EC REP

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CE 0197

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